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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,857	07/25/2001	Charles D. Petrie	PC10843AMAG	6128

7590

01/30/2003

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EXAMINER

JARVIS, WILLIAM R A

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 01/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/912,857

Applicant(s)

PETRIE ET AL.

Examiner

William R. Jarvis

Art Unit

1614

-- Th MAILING DATE of this communication appears on the cover sheet with the correspond nc address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 26-38 is/are pending in the application.
- 4a) Of the above claim(s) 22-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 26-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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1. Applicant's election without traverse of the species of claim 20 in Paper No. 8 is acknowledged.
2. Claims 22-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.
3. Claim 19 is objected to because of the following informalities: The claim's use of "Y" at the bottom of the claim on page 53 is in error and should be changed to "Y<sup>2</sup>" in order to properly correspond with the structure. Appropriate correction is required.
4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
6. Claims 1-21 and 26-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/41879 or WO 00/12047, each in view of WO 97/24369. (all references submitted by applicant with the exception of WO 97/41879, which has been cited on the attached Form PTO-

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892). The '879 application teaches the use of growth hormone secretagogues (hereafter, GHS) for enhancing or improving the quality of sleep, increasing in daytime alertness, enhancing cognitive function, and increasing memory retention; see particularly page 7, line 13 to page 8, line 10. The reference also suggests combining the GHS with applicant's preferred antidepressants, antipsychotics, and anxiolytic agents; see page 9, line 25 to page 10, line 23. The '047 application teaches the use of GHS for enhancing the return of patients having undergone surgery or immobilization to independent living status; see the abstract and the claims. The reference also suggests combining the claimed GHS with several of applicant's other GHS-related compounds of claim 26; see the first paragraph of page 24.

7. In addition, applicant's claims *appear* to differ in they specifically require improving functional health status of a patient, including improving daily living, energy level, mood, mental acuity, ability of the patient to perform in the workplace, health-related quality life, functional independence, and reducing social isolation. However, one skilled in the pharmaceutical arts would have been motivated to practice the claimed invention since the claimed attributes relate to outcomes achieved by practicing the methods of the primary references. For example, the use of GHS for enhancing the return of a patient to independent living status would most necessarily result in an improvement in functional health status, daily living, energy level, mood, ability of the patient to perform in the workplace, etc.

8. Applicant's claims (to the extent that they read on the elected species) differ from the primary references in that they require a GHS other than those taught by the prior art. However, the secondary reference teaches that applicant's elected compound is well-known as a GHS; see page 12, lines 20-25 and the abstract. In view of the prior art of record, one skilled in the art

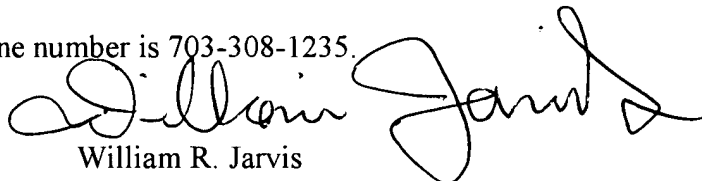
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would have been motivated to improve functional health status in a patient in need thereof, since the prior art teaches that applicant's elected compound is a well-known GHS, a class of compounds which are well-known in the art to be effective for the claimed use. To combine a naturaceutic such as ginkgo biloba, St. John's Wort, valerian, or melatonin with the claimed compounds is clearly obvious, since these natural compounds produce effects similar to the claimed cognitive-improving, antidepressant, mood-improving, and sleep-enhancing pharmaceuticals of the invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William R. Jarvis whose telephone number is 703-308-4613. The examiner can normally be reached on Monday, Tuesday, Thursday & Friday 7:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne C. Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



William R. Jarvis  
Primary Examiner  
Art Unit 1614

wrj  
January 27, 2003